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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,169	03/24/2005	Young-Min Lee	26689U	2581
20/529 7590 07/22/2008 NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314				
EXAMINER HURT, SHARON L				
ART UNIT 1648		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/529,169

Applicant(s)

LEE ET AL.

Examiner

SHARON HURT

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-38 is/are pending in the application.
- 4a) Of the above claim(s) 22-25 and 34-37 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-33 is/are allowed.
- 6) ☒ Claim(s) 7-11, 13-14, 16-21, 26-29 and 38 is/are rejected.
- 7) ☒ Claim(s) 12, 15-17, 31, 32 and 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

The amendments to the claims filed March 14, 2008 have been acknowledged and entered. Claims 10, 16, 27 and 29 are currently amended. No apparent amendments have been made to claims 16.

Status of the Claims

Claims 7-29 and new claims 30-38 are pending. Claims 22-25 have been withdrawn from consideration. New claims 34-37 are withdrawn from consideration because they are drawn to a nonelected invention. Claims 7-21, 26-33 and 38 are under examination.

Claim Objections

The objection of claims 12 and 15 because the claims contain multiple sequence identifiers, which are drawn to nonelected inventions **is maintained**.

New Claim Objections

Claims 16, 17, 31 and 32 are objected to because of the following informalities: The claims contain vectors represented by SEQ ID NO: 45 however the sequence identifiers are not listed in the claims. Appropriate correction is required.

Claim 38 is objected to because of the following informalities: The claim is dependent on a withdrawn claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The rejection of claims 16 and 17 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is maintained**. The specification has a reference to the deposit of vectors however the **address of the depository** is not listed in the body of the specification. The deposit must be referred to in the body of the specification and be identified by deposit (accession) number, name and address of the depository, and the complete taxonomic description. Appropriate correction is required.

The rejection of claims 26-27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is maintained**. The claims the phrase "elements originated from" which does not distinctly define the claimed invention because the term "elements" which is not defined in the specification is indefinite.

Claim Rejections - 35 USC § 102

The rejection of claims 7-10, 13, 18 and 29 under 35 U.S.C. 102(a) as being anticipated by **Mishin et al. is withdrawn**. Applicant's arguments, filed March 14, 2008, have been fully considered and are persuasive.

The rejection of claims 7-11, 13, 18-19 and 29 under 35 U.S.C. 102(b) as being anticipated by **Zhang et al. is withdrawn**. Applicant's arguments have been fully considered and are persuasive.

The rejection of claims 7-10, 13 and 18-21 under 35 U.S.C. 102(a) as being anticipated by **Sumiyoshi** et al. **is withdrawn**. Applicant's arguments have been fully considered and are persuasive.

The rejection of claim 27 under 35 U.S.C. 102(a) as being anticipated by **Chang** et al. **is withdrawn**. Applicant's arguments have been fully considered and are persuasive.

Claim Rejections - 35 USC § 103

The rejection of claims 7-11, 13, 18-21 and 26-29 under 35 U.S.C. 103(a) as being unpatentable over **Zhang** et al. and **Sumiyoshi** et al. in view of **Chang** et al. **is withdrawn**. Applicant's arguments have been fully considered and are persuasive.

The rejection of claims 7-11, 13-14, 18-21 and 29 under 35 U.S.C. 103(a) as being unpatentable over **Zhang** et al. and **Sumiyoshi** et al. in view of **Schumacher** et al. **is withdrawn**. Applicant's arguments have been fully considered and are persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. Claim 28 is drawn to a therapeutic agent comprising the JEV cDNA of claim 7 as effective ingredients. Claim 7 is drawn to a cDNA clone, which contains more than just the cDNA. Therefore claim 28 fails to particularly point out and distinctly claim the subject matter of the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-11, 13-14, 18-21, 26-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vector represented by SEQ ID NO: 45, pBAC^{SP6}/JVFLx/XbaI, comprising a full length infectious and genetically stable cDNA clone of JEV, does not reasonably provide enablement for a full length infectious and genetically stable cDNA clone of JEV. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states: "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring ingenuity beyond

that to be expected of one of ordinary skill in the art (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). They include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention: The claimed invention is drawn to a full length infectious and genetically stable cDNA clone of JEV encompassed in a BAC vector, pBAC^{SP6}/JVFLx/XbaI, represented by SEQ ID NO: 45 and having a SP6 or T7 promoter.

The state of the prior art: The art teaches that a full-length stable clone of JEV was not infectious. The art teaches that transcripts of the full-length PCR amplicon from the cDNA clone of JEV produced infectious virus. The art further teaches that transfection of cultured cells with the full-length cDNA amplicons or clone failed to produce infectious viruses as described by Zhang et al. (Journal of Virological Methods, August 2001, Vol. 96, No. 2, pages 171-182). Zhang et al. also teaches the transcript from the clone was non-infectious, however, the transcript from the amplicon of the clone was infectious (page 180, top of 2nd col.).

The amount of direction or guidance present and the presence or absence of working examples: Given the teachings of unpredictability in the art regarding the structural and functional differences in the JEV clone, detailed teachings are required in the disclosure to enable the full scope of the claims. These teachings are absent. Applicant's disclosure is limited to the cDNA clone of JEV in BAC vectors. The only working examples are for clones encompassed in BAC vectors and having a SP6 or T7 promoter. Examples are provided for the BAC vectors; however, no examples are provided for a full length infectious cDNA clone of JEV in the absence of a BAC vector.

The breadth of the claims and the quantity of experimentation needed: Because the invention encompasses full length infectious cDNA clones of JEV and because the specification fails to provide guidance as to how to use the claimed method for full length infectious cDNA clones of JEV other than full length infectious cDNA clones of JEV in BAC vectors, it would require undue experimentation by one of skill in the art to be able to practice the claimed invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18-21, 26-28 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (Journal of Virological Methods, Aug. 2001, Vol. 96, No. 2, pages 171-182).

The claimed invention is drawn to an infectious JEV RNA transcript synthesized from the cDNA clone, which is a full length infectious and genetically stable cDNA of JEV, wherein virus-unrelated nucleotides at its 3' end are removed. The claimed invention is also drawn to a cell transfected with the JEV RNA transcript. The claimed invention is also drawn to a diagnostic reagent and an anti-JEV vaccine containing elements originated from the JEV cDNA clone (described above). The claimed invention is also drawn to a therapeutic agent comprising the JEV cDNA.

Zhang et al. (hereinafter Zhang) teaches a technique to produce genome length cDNA stable clone from Japanese encephalitis virus (Abstract). The cDNA has a T7 promoter at the 5' end and a "run-off" transcript with vector sequences at either end (Abstract). The full-length amplicon was cloned into a vector under the SP6 promoter (Abstract). The RNA transcript was synthesized from the clone (page 174-175, connecting paragraph). Zhang teaches Japanese encephalitis virus genome lacks a poly-A tail at the 3'-terminus (page 176, 1st column). Zhang teaches RNA transcripts were transfected into BHK-21 cells (page 175, 1st column, 1st paragraph). Zhang teaches Japanese encephalitis virus has short untranslated regions (page 172, 1st column, 1st paragraph). Zhang teaches amplification of the full-length JEV genome by novel long RT-PCR protocol, transcription of infectious RNA directly from the amplicon and construction of a stable full-length JEV cDNA clone (page 173, 1st column, 2nd

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paragraph). Zhang also teaches the transcript from the clone was non-infectious, however, the transcript from the amplicon of the clone was infectious (page 180, top of 2nd col.).

Conclusion

Claims 12 and 15-17 and new claims 30-33 are free of the art. Claims 12 and 15-17 would be allowable if re-written in independent form. Claims 30-33 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON HURT whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Sharon Hurt

July 18, 2008

/Bruce Campell/

Supervisory Patent Examiner, Art Unit 1648